Department of Vermont Health Access
Pharmacy Benefits Management Program
DUR Board Meeting
Draft Minutes

March 28, 2023: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Joseph Nasca, MD		**Margot Kagan, PharmD**		**Mark Pasanen, MD**
	Anne Daly, PharmD		**Katharina Cahill, PharmD**		

Board Members Absent:

	Claudia Berger, MD				

DVHA Staff Present:

	Carrie Germaine		**Stacey Baker**		**Taylor Robichaud, PharmD**
	Lisa Hurteau, PharmD		**Michael Rapaport, MD**		

Change Healthcare Staff Present:

	Jeffrey Barkin, MD		**Laurie Brady, RPh**		**Michael Ouellette, RPh**

Guests/Members of the Public:

- Jon Ciruso, Eric Hyde, Erin Booth, Evie Kinsley (Novartis), Gregory Parks, Sunny Hirpara (AstraZeneca), Lisa Libera, Matt Harju, Melissa Abbott, Dana Monz, Odebiyi Olawemimo, Jai Persico (Neurocrine Biosciences), Tim McSherry, Annie Vong (Abbvie), Lindsey Walter, Joseph Ward (Abbvie)

1. **Executive Session:**
   - An executive session was held from 6:00 p.m. until 6:30 p.m.

2. **Introductions and Approval of DUR Board Minutes:**
   - Attendance was called and introductions of DVHA and Change Healthcare staff were made.
   - The February meeting minutes were accepted as printed.

3. **DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA**
   - DVHA is actively recruiting for several open board member positions. The current open positions can be filled by physicians and a mid-level practitioner.

4. **Chief Medical Officer Update: Michael Rapaport, MD, DVHA**

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- H. 222 was passed by the house. This is the "Opioid Overdose Prevention Act" bill that would have an impact on buprenorphine prescribing. If approved
    - Prior authorization (PA) would not be required for preferred buprenorphine formulations up to a dose of 24mg/day (current limit is 16mg/day) when prescribed from an office based opioid treatment (OBOT) program.
    - DVHA would be required to research the feasibility of implementing a "Gold Card" program for substance use disorder treatments. The concept would be to waive PA for prescribers with a >90% PA approval rate. The report would include both a financial impact and assessment from a safety/quality perspective; the report would be presented to the DURB and Clinical Utilization Review Board (CURB).
    - The current law decriminalizing the possession of buprenorphine is set to be repealed after a set timeframe. This bill would permanently extend this provision.

- The DEA is proposing new rules surrounding telehealth prescribing of controlled substances. After 30 days, an in-office visit is required for patients on buprenorphine. Current proposals are to potentially increase to 45 days.

- Over the past 3 years due to pandemic related rules, states have been required to keep people on Medicaid with a few exceptions. Vermont is preparing for the end of this requirement, and will begin a slow "unwind" over the next 12 months. Letters will be sent to patients letting them know that they need to re-enroll to continue coverage. Additional Information is available on the dvha.vermont.gov website.

Board Discussion: Dr. Nasca asked if Dr. Rapaport was able to provide testimony on H. 222. Dr. Rapaport noted that he was able to provide a short testimony. He felt that the legislature believes there are many perceived barriers to life-saving medication. Andy Miller stated that he would like more metrics and measurable results when it comes to monitoring diversion of buprenorphine. Dr. Rapaport noted that there is a VT young adults survey that included buprenorphine use in the questions for the first time.

5. **Follow-up Items from Previous Meetings: Laurie Brady, RPH Change Healthcare**

- None at this time.

Recommendation: None needed.

Board Decision: None needed.

6. **RetroDUR/ProDUR: Mike Ouellette, RPh and Laurie Brady, RPh, Change Healthcare**

    - Data Presentation: Concurrent Use of Opioids and Antipsychotics

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The prevalence of substance use disorder is elevated among those with schizophrenia. The lifetime prevalence is estimated at 47 to 59%, compared with 16% in the overall population, although rates vary by age, gender and other factors. Opioid use disorder is estimated in the schizophrenic population to be around 4-11%. Antipsychotics used to treat schizophrenia, are also used to treat other behavioral health conditions, such as mania associated with bipolar disease, depression, PTSD, obsessive-compulsive disorder and anxiety, which are also known to have a high rate of concurrent substance use disorder. The concern with co-prescribing opioids and antipsychotics is the risk of over-sedation, respiratory depression and death. The Centers for Medicare and Medicaid Services (CMS) has highlighted the need to monitor co-prescribing of opioids and antipsychotics for side effects and adverse reactions. Section 1004 of the SUPPORT ACT added a new section, 1902 of the Social Security Act, which requires states to implement drug review and utilization requirements including Opioid and Antipsychotic Concurrent Fill Reviews. According to the CMCS informational bulletin dated August 5, 2019:

> *This alert is supported by the FDA's warning of increased risk of respiratory and Central Nervous System (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur. Patients concurrently prescribed opioid and antipsychotic drugs benefit from increased coordination of care. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorders, and the treatment of pain. This review will encourage coordination of care for patients taking antipsychotic and opioid medication concurrently.*

Vermont conducted this RetroDUR in 2020 for calendar year 2019, and a drug-drug interaction Prospective DUR edit was added 1/13/21. While direct comparisons cannot be made given changing Medicaid eligibility, they looked at the data from each year to see if there might be fewer members taking both antipsychotics and opioids and if there are fewer providers prescribing both concurrently. We used paid, non-reversed Medicaid pharmacy and medical claims from Calendar Years 2020 and 2021, excluding members with Part D, VMAP and Healthy Vermonters coverage. We identified members, excluding those with a cancer diagnosis, who were prescribed an opioid for at least 90 days and examined how many were given an overlapping antipsychotic prescription along with continued use of the opioid for any duration and those with an overlap of more than 30 days. We also looked to see if the members, while prescribed both types of drugs, had ED visits or hospitalizations, and if the medications were prescribed by the same, or different, prescribers.

Comparison of members using opioids for 90 days or longer with overlapping antipsychotic use

	2019	2020	2021
Members with at least 90 days of opioid	1,686	1,411	1,357
Members on overlapping antipsychotic (any duration)	166	150	182
Members on overlapping antipsychotic for > 30 days	139	130	150

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Same prescriber for both drugs	102	86	94
Different prescriber for each drug class	133	105	130
Members with 50mg or less of Quetiapine as the antipsychotic	**	37	38
Number of ER visits/hospitalizations in members on both	122	95	50
Distinct members with ER visits/hospitalizations	69	169	75

*Note: When adding up the number of members with the same prescriber and those with different prescribers, the total may be more than the number of members in the analysis. This is because some members had multiple prescriptions, sometimes they had one prescriber, but not always.

** Numbers less than 25 are suppressed for privacy purposes

Recommendation: The previous analysis of calendar year 2019 resulted in 1,686 members with at least 90 days of opioid therapy; the current data shows a reduction in the yearly members treated with an opioid for at least 90 days, a 16.3% drop in 2020 and a 4% drop in 2021. The reduction in members taking opioid medications for over 90 days may be attributed to the nationwide efforts to curb opioid prescribing and reduce the number of members reliant on maintenance opioid therapy.

There was an analysis of the number of members receiving concurrent opioids for at least 90 days and overlapping antipsychotics for more than 30 days; this showed a small increase in the studied population for calendar year 2021, as well as an increase in the number of ER visits and hospitalizations. A prospective DUR edit was implemented on this combination of medications at the pharmacy level in January of 2021. This was in response to the RetroDUR analysis presented in 2020. The intent was to increase provider/pharmacist and patient awareness of the safety concerns with the combination.

DVHA and Change Healthcare will continue use of a prospective DUR edit to alert the dispensing pharmacist when the patient is prescribed an antipsychotic in combination with an opioid. This will provide additional information for patient counseling and provider outreach, if deemed necessary, and may contribute to improvement in care in this population. There were several members with over 6 ER visits or hospital admissions within the studied period. To better understand the cause of the ER visit or hospitalizations in this study population, DVHA will complete a chart review of members with over 6 ER visits or hospital admissions. Consideration for future analysis is to identify members in the hubs who are being treated with methadone and a concurrent antipsychotic prescription.

Board Discussion: Dr. Rapaport started to do a deeper dive into the diagnoses associated with the ER visit/hospitalization. Some were concerning and could potentially be related to concurrent use of opioids or antipsychotics or other co-morbid conditions.

Dr. Nasca asked about the locations of mental health treatment centers in Vermont and if this review included inpatient use. Dr. Rapaport explained that this review did not include inpatient use of the medications.

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Board Decision: The Board unanimously approved the above recommendations.

- Introduce: Compliance in Heart Failure

The treatment of heart failure has improved markedly over the last decade as the pathophysiology of heart failure is better understood and drugs with new therapeutic targets have been developed. Compliance with treatment is associated with improved life expectancy and decreased hospitalizations. Management of heart failure has become a specialty within cardiology, as treatment has become more complex. Currently, patients with heart failure accompanied by reduced ejection fraction (HFrEF) might be taking many medications, these medications can contribute to improving cardiac function and reducing associated health risks. These drugs fall into the classes of beta blockers (bisoprolol, metoprolol succinate, carvedilol), ACE inhibitors, ARBs (candesartan, valsartan, losartan), angiotensin receptor-neprilysin inhibitors (sacubitril/valsartan), SGLT-2 inhibitors, diuretics, aldosterone antagonists (spironolactone, eplerenone), If channel blockers (ivabradine). In some cases, hydralazine, statins, and anticoagulants are used adjunctively to improve cardiac function and reduce the risk of potential health complications. Medications are the most effective when taken as directed, and being prescribed multiple medications daily is a risk factor for poor compliance. General factors that contribute to poor medication compliance include side effect profiles, trouble swallowing pills, patient bias against medications and not insignificantly, the cost of medications. This analysis will examine medication compliance in patients with a diagnosis of heart failure who were prescribed medications from the mentioned classes in the calendar year 2022. The classes of drugs we will examine are the ACEs, ARBs, beta-blockers (bisoprolol, metoprolol succinate, carvedilol), and the angiotensin-receptor neprilysin antagonists. We will look at the medication possession ratio (MPR) for one year following the initial prescription of the selected medication. We will use paid, non-reversed Medicaid pharmacy and medical claims for adults with a heart failure diagnosis from 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. Only members with continuous Medicaid eligibility will be included in the analysis. Identify members with a diagnosis of heart failure and prescriptions for any of the listed drug classes used for treatment. Will look at the MPR for each drug prescribed for one year following the first prescription. This analysis will also identify the number of medications individual members are being prescribed. Finally, this analysis will evaluate compliance for each drug class to see if there are particular classes of medications that have poor adherence.

Board Decision: Dr. Barkin explained that a MPR of 0.8 or more is commonly used to assess a patient as adherent to prescribed medications.

7. **Clinical Update: Drug Reviews: Jeff Barkin, MD Change Healthcare and Laurie Brady RPh, Change Healthcare**

Biosimilar Drug Reviews:

- None at this time.

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Full New Drug Reviews:

- Sotyktu® (deucravacitinib)

Deucravacitinib, the active ingredient of Sotyktu®, is a tyrosine kinase 2 (TYK2) inhibitor. TYK2 is a member of the Janus kinase (JAK) family. Deucravacitinib binds to the regulatory domain of TYK2, stabilizing an inhibitory interaction between the regulatory and the catalytic domains of the enzyme. This results in allosteric inhibition of receptor-mediated activation of TYK2 and its downstream activation of Signal Transducers and Activators of Transcription (STATs) as shown in cell-based assays. JAK kinases, including TYK2, function as pairs of homo- or heterodimers in the JAK-STAT pathways. TYK2 pairs with JAK1 to mediate multiple cytokine pathways and also pairs with JAK2 to transmit signals as shown in cell-based assays. The precise mechanism linking inhibition of TYK2 enzyme to therapeutic effectiveness for its approved indication is not currently known. It is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It is not recommended for use in combination with other potent immunosuppressants. The safety and efficacy of Sotyktu® were assessed in 2 multicenter, randomized, double-blind, placebo- and active-controlled trials (PSO-1 and PSO-2) that included adults 18 years of age and older with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Efficacy was maintained through week 52 with continuous deucravacitinib. The authors concluded in both studies that deucravacitinib demonstrated superiority to placebo and apremilast across efficacy endpoints, while being well tolerated.

- Spevigo® (spesolimab-sbzo)

Spesolimab-sbzo, the active ingredient of Spevigo®, is an interleukin-36 receptor antagonist. It is a humanized monoclonal IgG1 antibody (mAb) against human IL-36R, produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. It inhibits interleukin-36 (IL-36) signaling by specifically binding to the IL36R. Binding of spesolimab-sbzo to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL-36 α, β, and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. The precise mechanism linking reduced IL36R activity and treatment of flares of GPP is unclear. It is indicated for treatment of generalized pustular psoriasis (GPP) flares in adults. The safety and efficacy of Spevigo® were assessed in a randomized, double-blind, placebo-controlled study that included adult subjects with flares of generalized pustular psoriasis (GPP). Subjects were randomized if they had a flare of GPP of moderate-to-severe intensity, as defined by: A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [the total GPPPGA score ranges from 0 (clear) to 4 (severe)], The presence of fresh pustules (new appearance or worsening of pustules), GPPPGA pustulation sub score of at least 2 (mild), and At least 5% of body surface area (BSA) covered with erythema and the presence of pustules.

Recommendation:

- Add Sotyktu® (deucravacitinib) with QTY LIMIT: 1 tablet/day to non-preferred.

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- Add Spevigo® (spesolimab-sbzo) with QTY LIMIT: 900 mg (15 ml) per dose to non-preferred.
    - Clinical criteria:
        - Add **Sotyktu** to the additional criteria for Cimzia, Cosentyx, Ilumya, Siliq, Skyrizi, Stelara, Tremfya
        - Add **Spevigo:** The patient is experiencing a moderate-to-severe intensity flare of generalized pustular psoriasis (GPP) as defined by: A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) or greater AND The presence of fresh pustules (new appearance or worsening of pustules) AND At least 5% of body surface area (BSA) covered with erythema and the presence of pustules AND The patient will not use concomitantly with other systemic immunosuppressants or topical agents AND Approval will be granted for a maximum of two 900mg doses, given 7 days apart.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

8. New Therapeutic Drug Classes

Potassium Reducing Agents

- No new drugs
- In 2015, the National Kidney Foundation published best practices in managing hyperkalemia in chronic kidney disease. They included a summary of interventions used for acute or chronic treatment of hyperkalemia. IV calcium is listed first and as having an onset of 1-3 minutes. The cation exchange resin SPS 25-50g was listed as having an onset of 1-2 hours and duration of ≥4-6 hours. Comments regarding this agent include:
    - Cases of intestinal necrosis, which may be fatal, and other serious GI adverse events have been reported.
    - May cause hypokalemia and electrolyte disturbances.
    - Cannot be used in medical emergencies.
    - Caution in patients with heart failure due to sodium load.
- The cation exchange resin patiromer was also listed at doses of 8.4g, 16.8g, or 25.2g. Its onset of action was listed as 7 hours and duration as about 48 hours. Comments regarding this agent include:
    - Binds with many other oral medications, separate the dosing of other oral medications by at least 6 hours.
    - Should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

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- May result in hypokalemia or hypomagnesemia.

Recommendation:

- No changes at this time.

Public Comment: Sunny Hirpara from AstraZeneca: Highlighted the attributes of Lokelma.

Board Decision: None needed.

9. **Therapeutic Drug Classes- Periodic Review:**

Angiotensin Modulators & Other Cardiovascular Agents

- Mavacamten, the active ingredient of Camzyos®, is an allosteric and reversible inhibitor selective for cardiac myosin. Mavacamten modulates the number of myosin heads that can enter 'on actin' (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of hypertrophic cardiomyopathy (HCM). Mavacamten shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with mavacamten reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures. It is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. The safety and efficacy of Camzyos® were assessed in a phase 3, double-blind, randomized, placebo-controlled, multicenter, international, parallel-group study (EXPLORER-HCM) that included adults (N=251) with symptomatic NYHA class II and III obstructive HCM, LVEF ≥55%, and Valsalva LVOT peak gradient ≥50mmHg at rest, or with provocation. A greater proportion of patients met the primary endpoint at week 30 in the Camzyos® group compared to the placebo group.

Beta Blockers, Anti-Anginals, & Sinus Node Agents

- Ranolazine, the active ingredient of Aspruzyo® Sprinkle, is an antianginal agent. Its mechanism of action has not been determined. Ranolazine has anti-ischemic and antianginal effects that do not depend upon reductions in heart rate or blood pressure. It does not affect the rate-pressure product, a measure of myocardial work, at maximal exercise. Ranolazine at therapeutic levels can inhibit the cardiac late sodium current (I_{Na}); however, the relationship of this inhibition to angina symptoms is uncertain. It is indicated for the treatment of chronic angina. May be used

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with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers. The studies included in the prescribing information for Aspruzyo® Sprinkle are the same as found in the ranolazine extended-release tablets prescribing information, which have the same indication as Aspruzyo® Sprinkle and have been available for numerous years. No new clinical studies were performed in the approval of Aspruzyo® Sprinkle, as the clinical studies in the prescribing information are the same as those found in the prescribing information for ranolazine ER tablets.

Calcium Channel Blockers

- Amlodipine, the active ingredient of Norliqva®, is a long-acting calcium channel blocker (CCB). It is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Serum calcium concentration is not affected by amlodipine. It is indicated for the treatment of: Hypertension, to lower blood pressure in adults and children 6 years of age and older. Coronary Artery Disease (CAD): For the symptomatic treatment of chronic stable angina. Norliqva® may be used alone or in combination with other antianginal agents. For the treatment of confirmed or suspected vasospastic angina (Prinzmetal's or Variant angina). Norliqva® may be used as monotherapy or in combination with other antianginal agents. In patients with recently documented CAD by angiography and without heart failure or an ejection fraction <40%, Norliqva® is indicated to reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure. The clinical studies in the prescribing information for Norliqva® were the same as those in the prescribing information for Norvasc®, brand name for amlodipine tablets. Norliqva® also has the same FDA approved indications as Norvasc® which has been available for numerous years and has an approved generic.
- Levamlodipine maleate is the maleate salt of levamlodipine, the pharmacologically active isomer of amlodipine, a long-acting calcium channel blocker (CCB). Amlodipine is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits

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the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Serum calcium concentration is not affected by amlodipine. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure. It is indicated for the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure. Levamlodipine may be used alone or in combination with other antihypertensive agents. The clinical studies in the prescribing information for levamlodipine regarding hypertension were the same as those in the prescribing information for Norvasc®, brand amlodipine tablets. Norvasc® has been available for many years and has an approved generic. It is an effective agent in the management of hypertension. Levamlodipine provides another treatment option.

Recommendation:

Ace Inhibitors and Combinations:

- Add Enalapril oral solution (age ≤ 12 years old) to preferred.
- Add Enalapril oral solution (age > 12 years old) to non-preferred.
- Move Epaned® (enalapril oral solution) for all ages to non-preferred.
- Remove Prinivil® (lisinopril), Tarka® (trandolopril/verapamil), and captopril/HCTZ. They have been discontinued.
    - Clinical criteria:
        - Update **Enalapril (Patients > 12 years old), Epaned Oral Solution:** patient has a requirement for an oral liquid dosage form (i.e. swallowing disorder, inability to take oral medications) AND for approval of Epaned, the patient must have a documented intolerance to the generic equivalent.

Angiotensin Receptor Blockers (ARBs) and Combinations:

- Move Telmisartan (compare to Micardis®) to preferred.
- Move Micardis® (telmisartan) to non-preferred.
- Move Candesartan to preferred.
- Move Telmisartan/hydrochlorothiazide (compare to Micardis HCT®) to preferred.
- Move Olmesartan/amlodipine (compare to Azor®) to preferred.

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- Clinical Criteria:
  - Add **Micardis** to Avapro, Benicar, Cozaar, Diovan, Edarbi criteria.
  - Update **Azor, Amlodipine/telmisartan, Exforge, Olmesartan/amlodipine:** The patient has had a documented side effect, allergy, or treatment failure to a preferred ARB/CCB combination product AND If brand name product with generic available, the patient has had a documented intolerance with the generic equivalent.

Beta Blockers:

- Remove Propranolol/HCTZ. It is no longer rebateable.

Calcium Channel Blockers

- Add Levamlodipine to non-preferred.
- Add Norliqva® (amlodipine) oral solution to non-preferred.
- Move Verapamil SR 100 mg, 200 mg, 300mg (compare to Verelan PM®) to non-preferred.
  - Clinical criteria:
    - Add Norliqva, Nymalize: patient has a medical necessity for a specialty dosage form (i.e. dysphagia, swallowing disorder) and the patient has a had a documented side effect, allergy, or treatment failure to Katerzia.

Central Alpha Agonists:

- Move Methyldopa tablets to non-preferred.
  - Clinical criteria:
    - Add Methyldopa: The patient has a documented side effect, allergy, or contraindication to two preferred central alpha agonists.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations with the removal of inability to take oral medications from Enalapril (Patients > 12 years old), Epaned Oral Solution criteria.

Recommendation:

Heart Failure

- Add new sub-category CARDIAC MYOSIN INHIBITORS. Note that all products require PA.
- Add Camzyos® (mavacamten) with QTY LIMIT: 1 capsule/day to non-preferred.
  - Clinical criteria:

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- Add **Camzyos:** The diagnosis or indication is symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) AND LVEF ≥ 55% AND Valsalva LVOT peak gradient ≥50mmHg at rest or with provocation AND The patient has a documented side effect, allergy, or treatment failure at a maximally tolerated dose to at least two of the following: Non-vasodilating beta blocker (e.g., atenolol, bisoprolol, metoprolol, nadolol, propranolol), Nondihydropyridine calcium channel blocker (i.e., diltiazem, verapamil), and Disopyramide AND The medication will not be used concurrently with disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker. Approval will be granted for 12 months. For reapproval, there must be a documented positive clinical response as supported by one of the following: Stable or reduction in New York Heart Association (NYHA) class AND Patient has a left ventricular ejection fraction of greater than or equal to 50%.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Recommendation:
Mineralocorticoid Receptor Antagonists

- Add CaroSpir® (spironolactone) oral suspension to non-preferred.
  - Clinical criteria:
    - Add **Carospir:** patient has a medical necessity for a specialty dosage form (i.e. dysphagia, swallowing disorder).

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Recommendation:
Coronary Vasodilators/Antianginals/Sinus Node Inhibitors

- Add Aspruzyo Sprinkle™ (ranolazine) granule with QTY LIMIT: 500 mg = 3 packets/day, 1000 mg = 2 packets/day to non-preferred.
  - Clinical criteria:

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- Add **Aspruzyo:** the patient has medical necessity for a non-solid oral dosage form.
- **Corlanor:**
  - *Diagnosis of Inappropriate Sinus Tachycardia:* Patient has persisting symptoms despite maximally tolerated doses of beta blockers or who have contraindication to beta blocker therapy.
  - *Diagnosis of Postural Orthostatic Tachycardia Syndrome (POTS):* The patient has a documented side effect, allergy, or treatment failure with at least 2 of the following medications: fludrocortisone, midodrine, beta blocker (metoprolol or propranolol), or pyridostigmine.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- **Anti-migraine: Triptans and CGRP Antagonist**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
Migraine/Acute Treatment
- Move Eletriptan (compare to Relpax®) with QTY LIMIT: 12 tablets/30 days and Frovatriptan (compare to Frova®) 2.5 mg with QTY LIMIT: 9 tablets/30 days to preferred.
- Move Relpax® (eletriptan) 20 mg, 40 mg with QTY LIMIT: 12 tablets/30 days to non-preferred.
  - Clinical criteria:
    - Update **Zolmitriptan Nasal Spray, Zomig Nasal Spray, Imitrex Nasal Spray, Onzetra Xsail, Tosymra:** patient has had a documented side effect, allergy, or treatment failure with Sumatriptan Nasal Spray. For Zolmitriptan Nasal Spray, the patient must also have a documented intolerance to the brand Zomig Nasal Spray.

Migraine/Prevention
- Clinical criteria:
  - Revise **Nurtec ODT, Quilipta, Vyepti:** The patient is 18 years of age or older AND The patient must have a documented side effect, allergy, or treatment failure to two preferred CGRP Inhibitors. Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must have documentation

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of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans. Pharmacy claims will also be evaluated to assess compliance with the medication. Clinical justification must be provided if there is an increase in triptan use noted in the patient's profile.

Public Comments: Annie Vong from Abbvie: Highlighted the attributes of Qulipta and Ubrelvy. Odebiyi Olawemimo from Teva yielded her time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- **Bile Salts & Biliary Agents**
  - No new drugs
  - No other significant clinical changes.

Recommendation:

- Remove Actigall. It has been discontinued.

Public Comments: None at this time.

Board Decision: None needed.

- **Botulinum Toxins**
  - No new drugs
  - No other significant clinical changes.

Recommendation:

- Update Additional criteria for Chronic migraine (Botox only): the patient has ≥ 15 headache days per month, of which ≥ 8 are migraine days, for at least 3 months AND the member has failed or has a contraindication to an adequate trial (≥ 60 days) of at least TWO medications for migraine prophylaxis from at least two different classes (tricyclic antidepressants, SNRI's, beta-blockers, or anticonvulsants). Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must have documentation of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans. Additional criteria for chronic sialorrhea (Myobloc and Xeomin): the patient has a documented side effect, allergy, treatment failure, or contraindication to at least two anticholinergic agents (e.g., scopolamine, glycopyrrolate).

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

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- **Lipotropics: Statins and Lipotropics: Other (Non-Statins)**
  - No new drugs
  - No other significant clinical changes.

Recommendation:

Bile Acid Sequestrants

- Move Colestipol granules, packets to non-preferred.
  - Clinical criteria:
    - Add **Colestipol granules, packets:** The patient has a documented side effect, allergy, or treatment failure with two preferred bile acid sequestrants.

Fibric Acid Derivatives

- Move Fenofibrate micronized capsule (compare to Lofibra® capsules) 67 mg, 134 mg, 200 mg and Fenofibrate tablets (compare to Lofibra® tablets) 54 mg, 160 mg to preferred.
  - Clinical criteria:
    - Add **All other non-preferred medications**: The patient has had a documented side effect, allergy, or treatment failure with two preferred fibric acid derivatives (If a product has an AB rated generic, there must have been a trial with the generic formulation.)

Statins

- Remove Pravachol® (pravastatin). It has been discontinued.

Miscellaneous/Combos

- Move Omega-3-acid ethyl esters (compare to Lovaza®) to preferred.
- Add Icosapent Ethyl (compare to Vascepa®) with QTY LIMIT: 4 caps/day to non-preferred.
- Move Ezetimibe/simvastatin (compare to Vytorin®) 10/10 mg, 10/20mg, and 10/40mg with QTY LIMIT: 1 tab/day to preferred.
  - Clinical criteria:
    - Update **Lovaza, Vytorin, Zetia**: patient must have a documented intolerance to the generic equivalent.
    - Add **Icosapent Ethyl, Vascepa**:
      - *Indication for use is severe hypertriglyceridemia:* The patient has pre-treatment triglyceride levels > 500 mg/dL AND The patient has a documented contraindication, side effect, allergy, or treatment failure to Omega-3-acid ethyl esters.
      - *Indication for use is cardiovascular risk reduction*: The patient has pre-treatment

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triglyceride levels > 150 mg/dL AND The patient is receiving adjunct therapy with a maximally tolerated high intensity statin AND For approval of icosapent ethyl, the patient has had a documented intolerance to brand Vascepa.

Public Comments: Evie Kinsely from Novartis: Highlighted the attributes of Leqvio.

Board Decision: The Board unanimously approved the above recommendations.

10. **Review of Newly-Developed/Revised Criteria:**

- **Miscellaneous ADHD and Narcolepsy Cataplexy Medications**

Recommendation:

  - Move Qelbree® (viloxazine hydrochloride) ER capsule with QTY LIMIT: 100 mg = 1 capsule/day, 150 mg = 2 capsules/day, 200 mg = 3 capsules/day; FDA maximum recommended dose = 600 mg/day to non-preferred.
- Clinical criteria:
  - The patient has had a documented side effect, allergy, contraindication, or treatment failure to one preferred stimulant or there is a history of substance abuse with the patient or family of the patient AND the patient has had a documented side effect, allergy, or treatment failure to atomoxetine.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

11. **General Announcements:**
- None at this time.

Board Discussion: Dr. Nasca asked about coverage of obesity agents approved for pediatric use. He stated that AAP recommends viewing obesity as a chronic condition. He also stated that he believes in rural areas it is difficult for Medicaid members to access the services of a nutritionist. Dr. Rapaport stated that DVHA is looking into a waiver for weight management programs. Anti-obesity agents are currently excluded from Medicaid coverage, but DVHA is exploring the possibility of coverage in the future. Lisa Hurteau explained the continued option for telehealth services and the ability of nutritional consultation from a remote perspective may be helpful.

12. **Adjourn:** Meeting adjourned at 8:20 p.m.

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